INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/08784

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K39/295 A61K39/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, MEDLINE, SCISEARCH, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 855 891 A (LOWY DOUGLAS R ET AL) 5 January 1999 (1999-01-05) abstract column 7, line 52 - line 64	1-6,20
A	WO 95 17209 A (SMITHKLINE BEECHAM BIOLOG ;MOMIN PATRICIA MARIE (BE); GARCON NATHA) 29 June 1995 (1995-06-29) cited in the application the whole document	
P,X	WO 99 45957 A (SMITHKLINE BEECHAM BIOLOG ;STEPHENNE JEAN (BE); WETTENDORFF MARTIN) 16 September 1999 (1999-09-16) claims 1,1-4,20	1-20

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 February 2001	07/03/2001

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer
Niemann, F

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 00/08784

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5855891 A	05-01-1999	US 5618536 A	08-04-1997
		US 5437951 A	01-08-1995
		AU 3828495 A	02-05-1996
		AU 717647 B	30-03-2000
		AU 4447899 A	28-10-1999
		EP 1018555 A	12-07-2000
		EP 0789766 A	20-08-1997
		JP 10506796 T	07-07-1998
		WO 9611274 A	18-04-1996
		AU 683220 B	06-11-1997
		AU 4847593 A	29-03-1994
		CA 2143845 A	17-03-1994
		EP 0662132 A	12-07-1995
		JP 8504087 T	07-05-1996
		WO 9405792 A	17-03-1994
		US 5756284 A	26-05-1998
		US 5709996 A	20-01-1998
		US 5871998 A	16-02-1999
		US 5744142 A	28-04-1998
		US 5716620 A	10-02-1998
		US 5985610 A	16-11-1999
WO 9517209 A	29-06-1995	AT 177322 T	15-03-1999
		AU 1316495 A	10-07-1995
		AU 687494 B	26-02-1998
		AU 1316695 A	10-07-1995
		AU 705521 B	27-05-1999
		AU 6803198 A	09-07-1998
		AU 705519 B	27-05-1999
		AU 6803298 A	09-07-1998
		CA 2179779 A	29-06-1995
		CN 1138298 A	18-12-1996
		DE 69417063 D	15-04-1999
		DE 69417063 T	28-10-1999
		DK 735898 T	23-08-1999
		WO 9517210 A	29-06-1995
		EP 0735898 A	09-10-1996
		EP 0868918 A	07-10-1998
		ES 2129801 T	16-06-1999
		GR 3029750 T	30-06-1999
		HK 1012243 A	12-05-2000
		JP 9506887 T	08-07-1997
		NZ 277802 A	27-04-1998
		SG 49257 A	18-05-1998
		SG 73578 A	20-06-2000
		SI 735898 T	30-06-1999
		US 6146632 A	14-11-2000
		ZA 9410176 A	17-11-1995
WO 9945957 A	16-09-1999	AU 3328399 A	27-09-1999
		BR 9908599 A	14-11-2000
		EP 1064025 A	03-01-2001
		NO 20004487 A	19-10-2000

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
SMITHKLINE BEECHAM
Attn. PRIVETT, Kathryn L.
Two New Horizons Court
Brentford
Middlesex TW8 9EP
UNITED KINGDOM

RECEIVED
- 7 MAR 2001
NEW HORIZONS COURT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference FB/B45198	Date of mailing *(day/month/year)* 07/03/2001
International application No. PCT/EP 00/ 08784	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A.	International filing date *(day/month/year)* 07/09/2000

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from th priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Carla Louro

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

BNSDOCID: <XSISA220NOENP4_I_>

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

BNSDOCID: <XSISA220NOENP4_I_>

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
FB/B45198		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/ 08784	07/09/2000	07/09/1999
Applicant		
SMITHKLINE BEECHAM BIOLOGICALS S.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

 a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

 [] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

 b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

 [] contained in the international application in written form.

 [] filed together with the international application in computer readable form.

 [] furnished subsequently to this Authority in written form.

 [] furnished subsequently to this Authority in computer readble form.

 [] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

 [] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [] **Certain claims were found unsearchable** (See Box I).

3. [] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

 [] the text is approved as submitted by the applicant.

 [X] the text has been established by this Authority to read as follows:

 COMBINED VACCINE COMPOSITIONS

5. With regard to the **abstract,**

 [X] the text is approved as submitted by the applicant.

 [] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figur of the **drawings** to be published with the abstract is Figure No. _____

 [] as suggested by the applicant.

 [] because the applicant failed to suggest a figure.

 [] because this figure better characterizes the invention.

 [X] None of the figures.

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PATENT COOPERATION TREATY

PCT

REC'D 31 OCT 2001

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
FB/B45198		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/08784	07/09/2000	07/09/1999
International Patent Classification (IPC) or national classification and IPC A61K39/00		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

 ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

 - I ☒ Basis of the report
 - II ☒ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
 - VI ☒ Certain documents cited
 - VII ☒ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27/03/2001	30.10.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Knudsen, H Telephone No. +49 89 2399 8696

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/08784

I. Basis of th report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-29 as originally filed

Claims, No.:

1-20 as originally filed

Drawings, sheets:

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item II

Priority

The priority appears to be allowable for all of the claimed subject-matter and the P-document mentioned in the International Search Report therefore does not appear to be relevant for the present International examination.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document/s/:

D1: US-A-5 855 891

D2: WO 95/17209

NOVELTY & INVENTIVE STEP:

5.1 D1 discloses a vaccine containing a virus-like particle (VLP). It is suggested to use human papilloma virus (HPV) and in particular HPV16. The VLP should have conformational L2 or L1 epitopes which may be fused to other proteins in order to provide a cost-effective vaccine with broad utility (ie a vaccine which provides protection against HPV and other pathogens as well). One of the fusion protein partners suggested is a protein from Herpes simplex virus (HSV). Thus, the vaccine compositions of claims 1 and 6 differ from D1 only in that the viral antigens are in conjunction with an adjuvant which is a preferential stimulator of Th1 cell responses.

However, it is common practice when designing vaccines for commercial use to select an adjuvant which enhances the immune response against the antigens present in the vaccine composition and there is no doubt that the particles described in D1, are foreseen as vaccines. The Th1 response through α-interferon is known to be associated with protective responses against intracellular pathogens (see eg D2, page 3, 5th paragraph). The selection of an adjuvant which preferentially stimulates the Th1 response in a vaccine which contains viral antigens therefore cannot be considered inventive. Thus, the subject-matter of claims 1 and 6 is not considered to involve an inventive step.

5.2 The use of QS21 and 3D-MPL as adjuvants in vaccines containing HSV gD antigen is disclosed in D2 (see claims and page 4, third paragraph). Considering the known adjuvant effect of QS21 and 3D-MPL in combination with HSV gD, it would be obvious to the skilled person to add these adjuvants to the combined preparation of HSV gD protein and HPV L1 or L2 antigen. Thus, claims 2-5 and 20 do not appear to be inventive in view of D1 and D2.

5.3 D1 (column 7, last paragraph) clearly mentions that more than one fusion partner may be present. Thus it would appear to be obvious to the skilled person that also other antigens may be presented together with the HSV and HPV antigens. The antigens mentioned in claims 7-12 and 14-19 are obvious selections from the range of antigens from known pathogens and these claims therefore do not add anything inventive to claim 1.

5.4 The use of aluminium hydroxide, aluminium phosphate, tocopherol and oil in water emulsions are adjuvants used routinely in the art and claim 13 therefore is not considered inventive either.

5.5 In addition, the IPEA is of the opinion that a number of combination vaccines are mentioned in the prior art and are even commercialised (eg. Priorix®) and that good responses to each antigen is obtained in these vaccines. Thus, the fact that the applicant has manufactured a combination vaccine, in which a response to each component can be obtained, is not unexpected and therefore is not sufficient to provide a basis for the acknowledgment of an inventive step.

INDUSTRIAL APPLICABILITY:

5.6 Claims 1-20 appear to be industrially applicable.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date* (day/month/year)
WO 99/45957	16.09.1999	04.03.1999	09.03.1998 23.06.1998

* Priority not checked

The above document may become relevant prior art in the Regional phase of the present application.

Re Item VII

Certain defects in the international application

7.1 Contrary to the requirements of Rule 5(a)(ii) PCT, the closest prior art document D1 is not identified in the description and the relevant background art disclosed therein is not briefly discussed.

7.2 Contrary to the PCT Guidelines C-II 4.16-4.17, registered trade marks have not been identified as such in the description.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number
WO 01/17551 A3

(51) International Patent Classification[7]: A61K 39/295, 39/39

(21) International Application Number: PCT/EP00/08784

(22) International Filing Date:
7 September 2000 (07.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9921146.8 7 September 1999 (07.09.1999) GB

(71) Applicant *(for all designated States except US)*: **SMITHKLINE BEECHAM BIOLOGICALS S.A.** [BE/BE]; rue de l'Institut, 89, B-1330 Rixensart (BE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **WETTENDORFF, Martine, Anne, Cecile** [BE/BE]; SmithKline Beecham Biologicals s.a., Rue de l'Institut 89, B-1330 Rixensart (BE).

(74) Agent: **PRIVETT, Kathryn, Louise**; SmithKline Beecham, Two New Horizons Court, Brentford, Middlesex TW8 9EP (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
27 September 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/17551 A3

(54) Title: COMBINED VACCINE COMPOSITIONS

(57) Abstract: Novel combined vaccine compositions are provided, comprising a herpes simplex virus (HSV) antigen and a HPV antigen and optionally in addition one or more of the following: an EBV antigen, a hepatitis A antigen or inactivated attenuated virus, a hepatitis B viral antigen, a VZV antigen, a HCMV antigen, a Toxoplasma gondii antigen. The vaccine compositions are formulated with an adjuvant which is a preferential stimulator of TH1 cell response such as 3D-MPL and QS21.